

Remarks/Arguments:

Claims 1-63 were submitted in the original application. A Restriction Requirement and an Election of Species Requirement were issued by the Office Action of June 2, 2004. By response of June 28, 2004, the applicants elected to prosecute Group I (claims 1-38 and 46-63) and further elected to prosecute Species A (claims 1-25.). These elections were made without traverse.

Claims 26-63 have been withdrawn from consideration and claims 39-45 have been cancelled without prejudice. Claims 1-25 therefore remain under consideration. The Office Action rejects claims 1-25 and objects to the drawings. The applicants respectfully traverse these rejections.

Objection to the Drawings

The applicants acknowledge with appreciation the courtesy of Examiner Deak's voicemail message of December 1, 2004, acknowledging that the formal drawings filed on January 29, 2002, have been received by the office and have been included in the file. Per this message, the applicants respectfully submit that the objection to the drawings should be withdrawn.

35 U.S.C. § 102(b)

Claims 1-5, 13, 16-18, 19-22, 24, and 25 were rejected under 35 U.S.C. § 102(b) as being anticipated by United States Patent 4,681,570 to Dalton (Dalton). The applicants respectfully submit that independent claim 1, as amended, is distinguishable from Dalton.

Dalton discloses a peritoneal catheter that takes the form of a flexible, elongated, perforated tube in a cylindrical helix configuration with its perforations along the tube wall. See column 2, lines 12-18. However, as indicated in the Office Action, Dalton does not teach or suggest a multi-lumen catheter.

In contrast, the applicants' invention, as claimed in amended claim 1, now recites "a septum that divides the interior into at least a first lumen and a second lumen." Because amended claim 1 now recites a limitation not taught or suggested by Dalton, the applicants respectfully submit that Dalton does not anticipate claim 1. Therefore, the applicants respectfully submit that this rejection should be withdrawn. In addition, because claims 4-5, 13, 16-18, 19-22, 24, and 25 depend, directly or indirectly, from independent claim 1, the applicants respectfully submit that the rejection of these claims should also be withdrawn.

35 U.S.C. § 103(a)

Dalton in view of Guest

Claims 6-11 and 14-15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Dalton in view of United States Patent 4,795,439 to Guest (Guest). Although claim 6 is cancelled by this amendment, to be fully responsive to the Office Action, the applicants hereby address the rejection of claim 6 as it pertains to amended claim 1. The applicants respectfully traverse this rejection and submit that the claims are patentable over Dalton in view of Guest because there is no motivation for the proposed combination.

Dalton, as discussed above, discloses a peritoneal catheter that takes the form of a flexible, elongated, perforated tube in a cylindrical helix configuration with its perforations along the tube wall. As noted above, Dalton does not teach or suggest a multi-lumen catheter. The device taught by Dalton is essentially a long-term catheter implanted for repeated use in the peritoneal cavity. See column 2, lines 6-11. It achieves dialysis by "flooding the peritoneal cavity with a sterile dialyzing fluid, allowing the fluid to absorb toxins from the blood stream by osmosis through abdominal capillaries, and then draining the spent fluid from the cavity." See column 1, lines 10-23. Dalton recognizes that its distal terminus (27) may be closed or open, but is preferably restricted or entirely closed in order to "force the flow of fluid... primarily through perforations (23)."

Guest, on the other hand, discloses a multi-lumen catheter for use in a vessel that incorporates a spiraling feature only with respect to its internal structure. See column 2, lines 7-13. Its outer configuration is essentially that of a straight tube. See Figure 2. There is no teaching or suggestion presented by Guest of a corkscrew-patterned tubular structure.

In contrast, the applicants' invention, as claimed, is a multi-lumen catheter having at least a portion of its outer tubular structure spirally formed into a corkscrew pattern and having a septum that divides the interior into at least a first lumen and a second lumen (see Figures 2A and 2B; page 6, lines 11-30).

The applicants respectfully submit that there is no teaching or suggestion for either reference to adopt or be combined with the structure disclosed in the other reference. Specifically, there is no suggestion to combine features of the Dalton single lumen peritoneal catheter, which is used to successively irrigate and drain an abdominal cavity, with features of the Guest straight multi-lumen vessel catheter, which is used for simultaneously introducing and removing fluids into and out of the bloodstream. Because the Dalton device is not used for simultaneously introducing and removing fluids, there would be no reason to modify such a device to provide multiple lumens, as is taught in Guest. Dalton seeks to provide a catheter "suitable for implantation and long-term use in the peritoneal cavity" and teaches that the pressure in the tube impels the helix to unwind, which "tends to free the tube perforations from organic deposits." The Guest catheter is not intended for implantation and long-term use, and Guest says nothing about organic deposits that would suggest modification to provide the helical core taught by Dalton. Accordingly, there is no teaching, suggestion or incentive supporting the combination of these references.

In *Ex parte Metcalf*, 67 U.S.P.Q.2d 1633 (May 2, 2003), the USPTO Board of Patent Appeals and Interferences cited caselaw to stress that there must be objective motivation to support an obviousness rejection. More specifically, the mere fact that teachings found in the prior art could be combined as proposed by an examiner does not make the combination obvious "absent some teaching, suggestion or incentive supporting the combination." *Id.* at 1635 (citing *Carella v. Starlight Archery and Pro Line Co.*, 231 USPQ 644, 647 (Fed. Cir. 1986)). It is respectfully submitted that the Examiner has failed to identify any such teaching, suggestion, or incentive to support his proposed combination. Accordingly, it is respectfully submitted that claim 1 is patentable over the art of record. Likewise, it is respectfully submitted that claims 2-24, which ultimately depend from claim 1, are also patentable over the art of record.

Dalton in view of Guest further in view of Fenton

Claim 12 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Dalton in view of Guest further in view of United States Patent 5,190,520 to Fenton, Jr. et al. (Fenton). The applicants respectfully traverse this rejection and submit that the claims are patentable over the cited references.

As above, the applicants respectfully traverse the rejection because there is no teaching or suggestion to combine the Dalton and Guest references. Moreover, the applicants' invention, as recited in claim 12, includes a feature that is neither disclosed nor suggested by Dalton, Guest, or Fenton taken individually or in combination. Claim 12 depends from claim 10 and adds the following feature:

wherein the first lumen extends distally further than a distal end of the second lumen.

The applicants' respectfully submit that the Office Action errs in its characterization of Fenton when it describes it as illustrating one lumen extending beyond an adjacent lumen. The applicants respectfully submit that, at best, Figure 1 in Fenton depicts a double lumen catheter incorporating a divider that extends beyond the opposing inflection points of the catheter's tubular outer wall to form a pointed midsection. This may be better understood when read in light of the (albeit scant) Fenton specification which indicates that "[t]he method [of manufacture] may further include the step of shaping the distal end of the catheter to produce a formed tip." See column 3, lines 21-23. The applicants respectfully submit that the best interpretation of the phrase "formed tip" is one having a pointed midsection.

Because the distal tip disclosed by Fenton does not teach or suggest an extended lumen as recited by applicants' claim 12, the applicants respectfully submit that *prima facie* obviousness cannot be established based on the cited references. Thus, the applicants respectfully submit that this distinction presents a basis for allowing claim 12.

Appln. No.: 10/059,925
Amendment Dated December 15, 2004
Reply to Office Action of September 30, 2004

BSI-491US

Conclusion

For at least the foregoing reasons, the applicants respectfully submit that pending claims 1-5 and 7-25 are allowable over the cited art. A notice to this effect is respectfully requested.

Respectfully submitted,


Rex A. Donnelly, Reg. No. 41,712
Phillip E. Gonzalez, Reg. No. 55,213
Attorneys for Applicants

PEG/mc

Dated: December 15, 2004

☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. 18-0350 of any fees associated with this communication.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to:
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:


Melissa Clemons 12/15/04

MC_I:\BSI\491US\AMEND_01.DOC